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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,784	01/24/2000	Robert A Mohror	PO4345USO PHI 1191	6271

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/28/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/489,784

Applicant(s)

Mohror

Examiner

FOX

Group/Art Unit

1638

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 7/2/02
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 1-32 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☒ Claim(s) 1-7 and 20 is/are allowed.
- ☒ Claim(s) 9-19 and 21-32 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2 July 2002 has been entered.

Applicant's amendments of 2 July 2002 have obviated all outstanding claim objections. However, the indication in the last office action that claims 8-10, 12-14, 16-18, 21-23, 25-27 and 29-31 were allowable is hereby WITHDRAWN in view of the following new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 8, 12-19, and 21-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8, 12, 16, 21, 25 and 29, and dependents, are indefinite for failing to further limit the claims on which they depend. The claims are drawn to a plant of a particular genotype and phenotype, which additionally comprises one or more transgenes or single gene conversions. Claims 8 and 21 are interpreted to include genetic manipulations of male sterility for the purpose of this rejection. However, once the plant has been genetically manipulated, it is no longer the same plant as that recited in the claim from which it depends. Drafting the claims in terms of a

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method of making plants comprising transforming the original plant with a particular transgene, and also submitting a product-by-process claim to claim the transformed product, would obviate this rejection. See the sample claims faxed by Supervisory Patent Examiner Amy Nelson on 2 August 2002 for copending and commonly owned application Serial No. 09/490,666.

Claims 8-19 and 21-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 12, 15, 25, 28, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. Claims 8, 16, 19, 21, 29, 32 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants. Claims 9-11, 13-15, 17-19, 22-24, 26-28 and 30-32 are also broadly drawn to any plant produced by crossing the exemplified hybrid line with any of a multitude of non-exemplified plants, or any descendant of the exemplified cultivar obtained by using that cultivar as one parent in a series of undisclosed crosses for an undisclosed number of generations and with undisclosed breeding partners. These claims are also broadly drawn to methods of using the transgenic plants, single gene conversion plants, or descendant plants.

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No guidance has been provided for the description or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

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Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus as broadly claimed. Given the lack of written description of the claimed products, any method of using them would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing. See Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111).

Claims 8, 12-19, 21 and 25-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 12, 15, 25, 28, and dependents are broadly drawn to any transgenic plant which contains any heterologous transgene of any sequence conferring any trait, and methods of using the transgenic plants. Claims 8, 16, 19, 21, 29, 32 and dependents are broadly drawn to any "single gene conversion" plant comprising one or more traits introgressed into the claimed variety by backcrossing or other traditional means, and methods of using these plants.

No guidance has been provided for the isolation or characterization of a multitude of heterologous coding sequences conferring a multitude of traits. In addition, no guidance has been provided for the introgression of any trait from a multitude of non-disclosed and uncharacterized parentals into the claimed variety, wherein said introgression should result in successful

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expression of the desired trait but should not interfere with the expression of the remaining traits whose combination confers patentability to the instantly exemplified variety, and which introgression should not introduce unwanted linked genetic material into the exemplified cultivar which would disrupt its patentably unique genetic complement. In addition, no guidance has been provided regarding the genetic or morphological characteristics of any of a multitude of breeding partners, or the resultant progeny.

Hunsperger et al (1996, U.S. Patent 5,523,520), Kraft et al (2000, Theor. Appl. Genet. 101:323-326), and Eshed et al (1996, Genetics 143:1807-1817) teach that it is unpredictable whether the gene or genes responsible for conferring a phenotype in one plant genotypic background may be introgressed into the genetic background of a different plant, to confer a desired phenotype in said different plant. Hunsperger et al teach that the introgression of a gene in one genetic background in any plant of the same species, as performed by sexual hybridization, is unpredictable in producing a single gene conversion plant with a desired trait (see, e.g., column 3, lines 26-46). In particular, Hunsperger et al teach that a gene conferring miniature plant stature which has been identified and genetically stabilized in one cultivar of *Petunia hybrida*, a member of the Solanaceae, does not confer a miniature phenotype when introgressed into the genome of a variety of other *Petunia hybrida* cultivars (see, e.g., column 3, lines 40-41).

Kraft et al teach that linkage disequilibrium effects and linkage drag prevent the making of plants comprising a single gene conversion, and that such effects are unpredictably genotype-specific and loci-dependent in nature (see, e.g., page 323). Kraft et al teach that linkage

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disequilibrium is created in breeding materials when several lines become fixed for a given set of alleles at a number of different loci, and that very little is typically known about the plant breeding materials, which contributes to the unpredictability of the effect. Eshed et al teach that in plants, epistatic genetic interactions from the various genetic components comprising contributions from different genomes may affect quantitative traits in a genetically complex and less than additive fashion (see, e.g., page 1815).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate the genes responsible for a multitude of non-exemplified traits, to evaluate the ability of these genes to be successfully expressed in various maize genetic backgrounds, or to obtain "single gene conversion" plants which contain a multitude of introgressed traits, but otherwise maintain all of the genetic and physiological and morphological characteristics of the parent plant. See also Applicant's traversal of the art rejection on pages 4-5 of the amendment of 2 July 2002, where Applicant admits that outcrossing the exemplified hybrid to another undisclosed plant is unpredictable.

Claims 11, 15, 19, 24, 28 and 32 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roundy et al (U.S. 5,773,682), as stated in the last office action.

Claims 1-10, 12-14, 16-18, 20-23, 25-27 and 29-31 remain deemed free of the prior art, given the failure of the prior art to teach or suggest a hybrid maize plant having all of the

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morphological and physiological characteristics of the exemplified corn plant, or methods of its use.

Claims 1-7 and 20 are allowed.

Applicant's arguments filed 2 July 2002 have been fully considered but they are not persuasive. Applicant urges that the art rejection is improper, given the failure of the prior art to teach or reasonably suggest the use of the exemplified hybrid as a starting material for the obtention of a maize plant with two of the claimed traits. The Examiner maintains that the rejected claims are product-by-process claims, wherein the prior art teaches a product that is indistinguishable from the claimed product, despite the alternate methods of making the product. The claimed individual traits are not unique to the exemplified hybrid, either in occurrence or level of expression or means of inheritance. See *In re Thorpe* cited previously. Thus, the Examiner was not relying upon Roundy et al to teach the exemplified hybrid as a starting material.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

August 24, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180/1638

